ADDITION OF DRAWINGS

Please add Figures 1 to 10, which are attached hereto, to the specification. These Figures were originally presented in the specification, as filed, at pages 17-24 and 26.

Attachments: New sheets: Figures 1 to 10 (10 pages)

REMARKS

Claims 19-36 are pending in this application. According to the Office Action of April 29, 2008, claims 19, 23-25 and 28-29 have been examined on their merits, and have been rejected. Claims 21, 22, 24-27 and 30-36 have been withdrawn by the Examiner from consideration as directed to non-elected subject matter. Applicants expressly reserve the right to file one or more continuation or divisional application(s) directed to the non-elected subject matter that is not rejoined with this application. The Office Action also asserts objections against the specification and abstract.

Applicants have amended the specification, the abstract, and claims 19 and 25. Applicants have also added figures 1 to 10, which are substantively identical to the figures found within the specification and have been deleted by this Amendment. No new matter has been added by these amendments. In view of these amendments and the remarks below, Applicants respectfully request reconsideration and withdrawal of the objections and rejections.

OBJECTION TO THE SPECIFICATION

The specification has been objected to for including graphical illustrations. Applicants have deleted the graphical illustrations and added figures 1 to 10, which are the graphical illustrations that were presented in the application as originally filed and that have been deleted by this Amendment. Accordingly, withdrawal of this objection is respectfully requested.

OBJECTION TO THE ABSTRACT

The abstract has been objected to for containing certain dashes. Applicants have deleted these dashes from the abstract. Accordingly, withdrawal of this objection is respectfully requested.

REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 19, 23-25 and 28-9 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Specifically, claims 19 and 25 have been rejected because the

Office Action contends that "it is unclear if the patient population is or is not suffering from trauma."[1] Applicants have amended claim 25 to depend from claim 23. Claim 23 recites that the trauma is surgery. Therefore, claim 25, as amended, clearly defines that the liquid composition is administered within 24 hours prior to the occurrence of the trauma (surgery). Furthermore, it is clear under the doctrine of claim differentiation that claim 19 is directed to patients who have or will suffer from a trauma.

Claim 19 has been rejected for its recitation of "guanosine equivalents" and "ribose equivalents." Applicants respectfully traverse this rejection as these terms are defined in the specification (for example, at page 5, lines 19-28). Notwithstanding this traversal, and without waiving protection for any equivalents, claim 19 has been amended to expedite examination by replacing "guanosine equivalents" and "ribose equivalents" with "guanosine", "guanosine salt", "guanosine-5'triphosphate", "guanosine ester", "ribose", "ribose nucleobase adduct", "ribose ester", and combinations thereof. Accordingly, withdrawal of this rejection is respectfully requested.

REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH, WRITTEN DESCRIPTION

Claims 19, 23-25 and 28-29 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action contends that precursors of guanosine are any compound involved in a chemical synthesis or biological pathway including guanosine. The Office Action further contends that "the precursors are not required to share any structural feature with guanosine. Hence, there is substantial variability in the genus."[2] In support of this rejection, the Office Action cites *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), a case involving DNA that was claimed only by function, for the proposition that the instant application contains inadequate support under Section 112. *Eli Lilly* was based on the specific type of invention and its holding is not applicable to this case. The Examiner is urged to review the more recent case of *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1123- 24 (Fed. Cir. 2004).

[1] Office Action at page 5.
[2] Office Action at page 8.

In view of these cases, Applicants respectfully traverse this rejection. Notwithstanding this traversal and without waiving any equivalents, claim 19 has been amended to expedite examination by replacing "guanosine equivalents" and "ribose equivalents" with "guanosine", "guanosine salt", "guanosine-5'triphosphate", "guanosine ester", "ribose", "ribose nucleobase adduct", "ribose ester", and combinations thereof. Accordingly, withdrawal of this rejection is respectfully requested.

REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, ENABLEMENT

Claims 19, 23-25 and 28-29 have been rejected under 35 U.S.C. § 112, first paragraph, as not enabled by the specification. The Office Action contends that the specification does not enable one to ***prevent*** multiple organ dysfunction.[3]

When asserting an enablement rejection, the Patent Office bears the burden of setting forth a reasonable explanation as to why it believes that the claims are not enabled by the specification. *In re Wright*, 999 F.2d 1557, 1561-1562 (Fed. Cir. 1993); *In re Stoughton*, No. 2005-2235, App. No. 09/038,894, 2006 WL 1665412 at *4 (BPAI 2006). Precise predictability is not the standard to employ. *In re Corpet*, No. 2004-1790, App. No. 09/836,971, 2004 WL 2733634 (BPAI 2004).

The rationale set forth in the Office Action is similar to one reversed by the Board in *Corpet*. In *Corpet*, the examiner rejected claim 12 as not enabled by the specification. 2004 WL 2733634 at *1. Claim 12 recited "[a] method of preventing colon or rectum cancer comprising administering to a mammal a therapeutically effective amount of a non-fermented osmotic polyol laxative." *Id.* The rationale for rejecting claim 12 was based on the argument

> that the recitation of preventing "extend[s] the treatment to those patients in which rectal and colon cancers may occur at any point of time in [the] future." [Citation omitted.] With respect to the state of the art, the examiner apparently recognizes that "[t]he state of the art recognizes that increased intake of dietary fibers contribute to the increased bowel movements and thus result in lowering the risk of colon cancers," but asserts that "the art does not teach or recognize a complete prevention of the above claimed cancers." [Citation omitted.] Finally, with respect to guidance of the specification and

[3] Office Action at page 11.

> examples, the examiner focuses on the lack of teaching of an understanding of when the cancer may occur.

Id. at *1. The Board determined that the examiner's rationale required "precise predictability as to the time when the colon or rectal cancer will appear, and also appears to require 100% prevention. That is not, however, a requirement under 35 U.S.C. § 112, first paragraph." *Id.* at *2. Accordingly, the Board reversed the rejection. *Id.* at *3.

The Board reversed a similar rejection in *In re Goldenberg*, App No. 08/183,381, 2002 WL 31105508 (BPAI 2002). In *Goldenberg*, the examiner argued that "'[a]pplicant broadly claims an anti-idiotype vaccine to prevent cancer, AIDS and malaria, but the specification fails to enable the vaccine(s) and effectively teach how to make and/or use said vaccines to achieve this.'" *Id.* at *3. The Board held that this

> failed to provide the evidence necessary to demonstrate that appellants' disclosure does not enable their claimed invention. While some of the claimed combinations may be inoperative, the examiner failed to establish that the number of inoperative combinations is so significant, that one of ordinary skill in the art would have to experiment unduly in order to practice the claimed invention.

Id. at *4. Like *Corpet*, the Board in *Goldenberg* reversed the rejection because the examiner required 100% predictability, which is not the standard for enablement.

Like the rejections in *Corpet* and *Goldenberg*, this rejection is based on precise predictability. The specification shows a beneficial effect when the recited composition is administered as a pre-operative supplement prior to surgery.[4] One of ordinary skill could extrapolate from this data and find that the specification provides sufficient evidence for one to prevent multiple organ dysfunction.

The Office Action contends that the Applicants have not provided any examples of mammals suffering from trauma.[5] However, examples 8 and 9 discuss experiments where rats underwent surgery, which is a type of trauma according to the specification.[6] Example 8 shows the beneficial effect of the recited composition on liver function and multiple organ dysfunction. Example 9 shows the effect the recited composition

[4] For example, see specification at page 16, line 16 to page 24, line 33.
[5] Office Action at page 13.
[6] See specification at page 16, line 16 to page 24, line 33; see also claim 23.

has on kidney function and plasma urea levels. These examples demonstrate that the recited composition can prevent multiple organ dysfunction. Moreover, with respect to multiple organ dysfunction, there is no relevant difference between surgery and multiple gunshot wounds.

Therefore, one would not require undue experimentation to prevent multiple organ dysfunction syndrome in a mammal suffering from trauma. As the data provided in the specification suggests, one would simply administer the recited composition, and prevent multiple organ dysfunction.

Accordingly, reconsideration and withdrawal is respectfully requested.

REJECTION UNDER 35 U.S.C. § 102

Claims 19, 23-25 and 28-29 have been rejected under 35 U.S.C. § 102(b) as anticipated by either Alexander[7] or Masor.[8]

Claim 19 is directed to a method of preventing multiple organ dysfunction in a mammal suffering from trauma. The method comprises administering an aqueous liquid composition. The aqueous liquid comprises digestible water soluble carbohydrates and a liver guanosine-5'-triphosphate (GTP) increasing component within 24 hours of the occurrence of the trauma. The liver GTP increasing component is selected from the group consisting of guanosine, guanosine salt, guanosine-5'triphosphate, guanosine ester, ribose, ribose nucleobase adduct, ribose ester, and combinations thereof.

Alexander is directed to enhancing host defense mechanisms. The Office Action contends that Alexander teaches compositions "suitable for patients who suffer from post-surgical trauma or trauma (column 5, lines 28-36)."[9] However, Alexander is not directed to multiple organ dysfunction. Instead, it is directed to compositions "suitable for use in patients who suffer from depressed host defense mechanisms, e.g. in patients who suffer from depressed host defense mechanisms as a result of post-surgical trauma, cancer, chemotherapy/radiation therapy, sepsis, trauma, burns, immunosuppressive drug therapy,

[7] United States Patent Number 5,231,085 to Alexander *et al.* ("Alexander").
[8] United States Patent Number 5,602,109 to Masor *et al.* ("Masor").
[9] Office Action at page 15.

malnutrition, transfusion induced immunosuppression and the like."[10] This is not multiple organ dysfunction.

Similarly, Masor is directed to enhancing the immune system of a human via infant formulae.[11] Like Alexander, this reference also does not disclose using the recited composition to prevent multiple organ dysfunction.

In order for a reference to anticipate a claimed invention, it must teach each and every limitation recited in the claim. In this case, Alexander and Masor both fail to teach using the recited composition to prevent multiple organ dysfunction. Accordingly, reconsideration and withdrawal are respectfully requested.

Furthermore, the Office Action contends that the recited invention is a method of prevention, and therefore, "any patient population is available for preventative administration."[12] However, claim 19 recites that it is a method of preventing multiple organ dysfunction ***in a mammal suffering from trauma.*** Thus, the patient must be suffering from or about to suffer from trauma, and therefore be at risk to multiple organ dysfunction.

For these reasons, Applicants respectfully request reconsideration and withdrawal of these rejections.

REQUEST FOR REJOINDER

The Office Action acknowledges that Applicants elected Group II, claims 19-29, with traverse, and that the GUANOSINE and GLUCOSE species were also elected with traverse.

With regard to the species, Applicants respectfully request that claims 20, and 24-27, which are drawn to non-elected species, be examined and allowed because an

[10] Alexander at column 5, lines 28-36.
[11] Masor at abstract.
[12] Office Action at page 16.

allowable generic claim is pending in this application.[13] The Applicants further request that the non-elected claims 30-36 be rejoined.[14]

CONCLUSION

In view of these amendments and remarks, Applicants respectfully request that the objections and rejections be reconsidered and withdrawn, that claims 19, 21-23 and 28-29 be allowed, and that claims 20, 24-27 and 30-36 be rejoined.

Respectfully submitted,

THE WEBB LAW FIRM

By _____

William H. Logsdon
Registration No. 22,132
Attorney for Applicants
436 Seventh Avenue
700 Koppers Building
Pittsburgh, PA 15219
Telephone: (412) 471-8815
Facsimile: (412) 471-4094
E-mail: webblaw@webblaw.com

[13] See MPEP § 809.02(a).
[14] See MPEP § 821.04.